TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: 0147-0220P

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 09/743577 NEW

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/DE99/02202	July 15, 1999	July 15, 1998

TITLE OF INVENTION

SKIN AND TISSUE CARE AND/OR TREATMENT PREPARATION

APPLICANT(S) FOR DO/EO/US

Herbert SCHLACHTER

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39 (1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☒ has been transmitted by the International Bureau. WO 00/03689
   c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ A translation of the International Application into English (35 U.S.C. 371(c)(3)).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(2)).
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
8. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98./1449 Form, International Search Report in German w/o references

12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.

13. ☒ A FIRST preliminary amendment.
    ☐ A SECOND or SUBSEQUENT preliminary amendment.

14. ☐ A substitute specification.

15. ☐ A change of power of attorney and/or address letter.

16. ☒ Other items or information:
    International Application in German
    Article 34 Claims
    Zero (0) sheets of formal drawings

526 Rec'd PCT/PTO 12 JAN 2001

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
09/743577	PCT/DE99/02202	0147-0220P

17. ☒ The following fees are submitted:	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a)(1)-(5):		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1,000.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$860.00**		
International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**		
International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 860.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$ 130.00	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total Claims	18 - 20 =	0	X **$18.00**	$ 0.00	
Independent Claims	3 - 3 =	0	X **$80.00**	$ 0.00	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		Yes	+ **$270.00**	$ 270.00	
TOTAL OF ABOVE CALCULATIONS =				$ 1,260.00	
Reduction of ½ for filing by small entity, if applicable. Applicant claims Small Entity Status in accordance with 37 CFR 1.27.				$ 630.00	
SUBTOTAL =				$ 630.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐20 ☐30 months from the earliest claimed priority date (37 CFR 1.492(f)). +				$	
TOTAL NATIONAL FEE =				$ 630.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
TOTAL FEES ENCLOSED =				$ 630.00	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ **630.00** to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account. No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 02-2448.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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Reg. No. 37,011

SIGNATURE

for MURPHY, GERALD M., JR.
NAME

#28,977 (GMM)
REGISTRATION NO.

/djm 1/12/01

(REV. 12/11/2000)

PATENT
0147-0220P

IN THE U.S. PATENT AND TRADEMARK OFFICE

Applicant:	SCHLACHTER, Herbert		
Int'l. Appl. No.:	PCT/DE99/02202		
Appl. No.:	New	Group:	
Filed:	January 12, 2001	Examiner:	
For:	SKIN AND TISSUE CARE AND/OR TREATMENT PREPARATION		

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, DC 20231

January 12, 2001

Sir:

The following Preliminary Amendments and Remarks are respectfully submitted in connection with the above-identified application.

AMENDMENTS

IN THE SPECIFICATION:

Please amend the specification as follows:

Before line 1, insert --This application is the national phase under 35 U.S.C. § 371 of PCT International Application No. PCT/DE99/02202 which has an International filing date of July 15, 1999, which designated the United States of America.--

IN THE CLAIMS:

Please amend the claims as follows:

Claim 6, line 1, change "any one of claims 2 to 5" to --claim 2--

Claim 7, line 7, change "any one of claims 2 to 6" to --claim 2--

Claim 8, line 1, change "any one of claims 2 to 7" to --claim 2--

Claim 9, line 1, change "any one of claims 2 to 8" to --claim 2--

Claim 10, line 1, change "any one of claims 2 to 9" to --claim 2--

Claim 11, line 1, change "any one of the claims 2 to 10" to --claim 2--

Claim 12, line 1, change "any one of claims 2 to 11" to --claim 2--

Claim 13, line 1, change "any one of claims 3 to 12" to --claim 3--

Claim 14, line 1, change "any one of claims 2 to 13" to --claim 2--

Claim 15, line 1, change "any one of claims 3 to 13" to --claim 3--

Claim 16, line 1, change 1, "any one of claims 2 to 13" to --claim 2--

REMARKS

The specification has been amended to provide a cross-reference to the previously filed International Application.

The claims have been amended to remove the Improper multiple dependencies and to place the application into better form prior to examination.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By Raymond C. Stewart (Reg. No. 21,066)
for Gerald M. Murphy, Jr., #28,977

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GMM/djm
0147-0220P

(Rev. 04/19/2000)

Skin and tissue care and/or treatment preparation

The invention relates to a skin and tissue care and/or treatment preparation. In particular, the invention relates to a preparation for care, protection and prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue, wherein said preparation comprises at least one salt selected from alkali and alkaline earth metal salts and other minerals and is characterized in that it contains at least one amino acid and zinc oxide and/or an inorganic peroxide, preferably magnesium peroxide or sodium peroxide. Optionally, the inventive preparation can additionally contain an adstringent, a binding and adhesive agent, a humectant, an ethereal oil, tego-betaine, secondary plant substances such as epigallocatechines, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and/or antimicrobial components.

Natural nutrients are essential for the health of cells and body. They serve to maintain and regenerate the skin as well as to stimulate metabolism and oxygen supply of the cells. The extensive significance of nutrient supply becomes also more and more important in the field of skin care, cosmetic and dermatology. Hormonal modifications, predisposition, an unbalanced and wrong diet and unhealthy habits, especially smoking and lack of exercise, lead to typical manifestations of the skin, such as tissue modifications, tissue deformations and cellular metabolic disturbances. A well-aimed supply of nutrients harmonizes metabolism and thus results in a natural, physiological equilibrium of the cells.

It is generally known that vitamins, minerals and trace elements are indispensable to the nutrient supply of the skin. Proteins which are built up of amino acids are an important building component for cells and endogenous active substances, such as enzymes and certain hormones. Polyunsaturated fatty acids, secondary plant substances, such as flavonoids and epigallocatechines, and liposomes in general are becoming more and more important for health and fitness. Vitamins, minerals and trace elements, polyunsaturated fatty acids and bioactive plant substances such as flavonoids are essential regulators in the metabolism and protective nutrients for the health of the skin.

Vitamins are essential nutritional components which, for the normal functions of heterotrophic organisms, have to be supplied more or less obligatorily and in correspondence to the needs, since they are only available either from external

sources or under the influence of millieu factors (e.g. intestinal flora). Their specific biocatalytic effect is based on the replacement of the active groups of enzymes which are subject to metabolical consumption. From science it is for example known that B-type vitamins contribute to the intermediary metabolism as coenzymes and that vitamins C, E and β-carotene mainly function as antioxidants. Deficiencies resulting from insufficient supply or resorption, disorders of the intestinal flora or of metabolism, antivitamin-effect or increased consumption lead to hypovitaminosis and avitaminosis.

Furthermore, minerals and trace elements are essential regulators in the metabolism. Zinc, magnesium and the B-type vitamins are high-performance elements as they activate enzymes and thus allow the metabolism of carbohydrates, fats and protein substances. Silicon has a favorable effect on stability and maintenance of the skin. Furthermore, it is scientifically undisputed that zinc has an essential function in the immune system and in the metabolism of the skin.

Polyunsaturated fatty acids contain linolic acid, and α- and γ-linolenic acid, which are important starting substances for biologically active regulators in the metabolism, such as eicosanoids and prostaglandins, and which ensure a healthy equilibrium in the metabolism. Currently, eicosanoids and prostaglandins, also referred to as tissue hormones, are being intensively examined by scientists with regard to their health stabilizing effect. The favorable influence of the polyunsaturated fatty acids on the healthy skin function as well as on inflammatory processes is known. Furthermore, it is known that polyunsaturated fatty acids of the type of the ω-3-(eicosapentaenoicacid, α-linolenic acid) and ω-6-fatty acids (linolic acid, γ-linolenic acid) have favorable effects on neurodermatitis and psoriasis as well as regeneration processes induced by physical strain during exercise. The importance of the so-called secondary plant substances, in the special branch of science also referred to as bioactive plant substances, for health is now being examined as well. Bioflavonoids, which effectively support the effects of vitamin C with regard to the power of resistance, vascular walls and connective tissue also count among these natural plant substances. Furthermore, it is known that bioflavonoids have antioxidant properties and that they thus synergistically complement the effect of the vitamins C, E and β-carotene.

With regard to biosynthesis aspects, amino acids are divided into essential, semi-essential and non-essential amino acids. In addition to their function as building blocks for proteins, amino acids are precursors of biologically effective compounds. Amino acids are i.a. described in L. Stryer, Biochemie, Spektrum Akademischer Verlag, Oxford, 1994 and in Römpp Lexikon Chemie, editor J. Falbe and M. Regitz, keyword "amino acids", Thieme Verlag, 1996 and bibliographic references cited therein.

Liposomes are particles surrounded by single or multi-layered phospholipid double membranes which can be loaded with hydrophilic pharmaceutical molecules in the inner, aqueous phase. By using them as pharmaceutical carriers, a selective local enrichment of active substances and a delayed release of active substances can be achieved.

Numerous preparations for treating and preventing mycotic, microbic, pathologic and other tissue-damaging manifestations and effects, tissue modifications, tissue deformations and cellular metabolic disturbance and other forms of damage to human tissue are commercially available. There are, for example, various therapeutic approaches for treating skin and connective tissue problems. The success of many of these preparations is, however, questionable, as these preparations are unable to reach the damaged cells and/or to act in the damaged cells. Furthermore, many of the products that are commercially available do not take the active mechanism discovered by scientists into account in which the cell is remineralized in a natural way and metabolism is stimulated so that the natural inner pressure of the cell is reestablished, the cell volume is normalized and fat and slag substances are effectively displaced and secreted.

DE-OS-196 22 708 describes a phytobiological preparation for the topical and parenteral incorporal application for preventing, caring for and treating various pathological and other endogenic and exogenic effects, modifications and diseases, as well as for maintaining, healing and reestablishing the homeostasis in and at animal and human organs and soft tissue, characterized in that it contains the following components:

(a) one or more ion-containing components and mineral salts,

(b) one or more adstringent components, one or more binding agents, a humectant and one or more ethereal oils, and

(c) optionally one or more vegetable extracts, a gelling agent, acid bondings, hyaluronidase or other suitable components in an amount between 0.01 and 20%. This preparation can optionally contain calendula, hamamelis or other homeopathic components, amino acids, enzymes, vitamins, electrolytes, dyes, wax, emulgators, starch, vaseline, paraffines, oils, acids, fats, vegetable mixtures and extracts, urea, sulfate compounds, etc. Neither does the patent application disclose examples of amino acids nor are amino acids used in the examples.

An object of the present invention is to provide a skin and tissue care and/or treatment preparation which distinguishes itself by a quick effect, excellent tolerance, a broad field of application and particularly intense deep action. In particular, the preparation is supposed to be applicable for care, protection, prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue. The preparation according to the invention is supposed to take into account research results concerning the diffusion of ions through ion channels into the intracellular space and improve microcirculation in the cell.

An object of the present invention is solved by the provision of a composition comprising the following components:

(a) at least one salt selected from alkali and alkaline earth metal salts and other minerals,
characterized in that it contains
(b) at least one amino acid, and
(c) zinc oxide and/or an inorganic peroxide.

Preferably zinc oxide, magnesium peroxide or sodium peroxide are used as component (c) of the composition.

In preferred embodiments the inventive preparation can additionally comprise, each independent of the other, at least one adstringent agent, a humectant, an ethereal oil, tego-betaine, secondary plant substances such as flavonoids and epigallocatechines, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and antimicrobial components. Furthermore, it can comprise usual carriers and adjuvants as well as binding and adhesive agents and usual solvents.

In a preferred embodiment the preparation of the present invention is topically used through direct application at the site of action.

The preparation of the present invention takes into account new research results concerning the diffusion of ions through ion channels into the intracellular space. Hereby ions of mineral salts penetrate through the upper skin layers deep into the cell interior of hypoderm, connective tissue and fat cells. The inventive preparation uses i.a. the principle of ion exchange between cell interior and cell exterior using high osmotic pressure which is created by the combination of active substances of the preparation. In this process, however, the amino acids, which help the ions to more effectively overcome the natural barriers of the cell membranes to reach the cell interior, which is the actual site of action, play an important role.

The inventive composition is in particular still effective if the functional capability of the cell regarding ion activity is limited. Particularly when the ion activity is limited, the amino acids act as additional carriers for substances which must be infiltrated for the intracellular activity in order to be functionally effective therein. It has been found that the combination of amino acids and zinc oxide and/or inorganic peroxides improves the microcirculation in the cell, compared to the use of salts. The improvement can visually and biometrically be shown. If only salts are used, an increase of the microcirculation in the cell abruptly falls back to the starting value after about 1.5 hours. When the inventive composition comprising the combination of amino acids and zinc oxide and/or inorganic peroxides is used, the improvement of microcirculation is, compared to the use of salt, greater, more steady, lasts longer and approaches the starting value slowly. This allows a better infiltration of agents into and a better distribution of agents in the cell, which increases the synergistic effect.

Furthermore, in contrast to the salts alone, a combination of salts and amino acids has a greater positive effect on the skin physiology. This affects in particular the moisturing factor, the pH value and the sebometry of the skin. When salts are used in combination with amino acids, the salts are infiltrated into the cell more effectively than without amino acids, as amino acids are, on the one hand, a key for the cell membranes and, on the other hand, support and increase the activation of the ion channels.

Alkali and alkaline earth metal salts and other minerals are essential regulators in the metabolism. In the present invention all known alkali and alkaline earth metal salts and minerals, which can also be present as trace elements, can be used. Preferred representatives of the group of alkali and alkaline earth metal salts and minerals that can be used in the present invention are sodium, potassium, magnesium, calcium, silicon, zinc, manganese, copper, iron, fluorine, chlorine, bromine, iodine and phosphorus. Preferred trace elements are accidental trace elements, such as silver, gold, aluminum, barium, bismuth, cadmium, chrome, nickel, lead, tin, titanium and vanadium, and essential trace elements, such as chrome, cobalt, copper, fluorine, iron, iodine, manganese, molybdenum and selenium, which are present in, for example, enzymes, chromoproteines and hormones as constituents. The amount of the alkali and alkaline earth metal salts and other minerals in the inventive preparation is preferably 10 to 90 percent by weight, more preferably 20 to 85 percent by weight, particularly in topically applicable agents 10 to 30 percent by weight, more preferably 10 to 25 percent by weight, based on the sum of all components in the preparation, depending on the desired osmotic effect. The alkali and alkaline earth metal salts and the other minerals are added in the form of usual salt compounds or organic compounds. For example, sodium, potassium and magnesium are preferably added in the form of their chloride salts, sodium and calcium in the form of phosphates.

The adstringent agents which are optionally used in the present invention comprise usual compounds for this purpose. Tannin, hamamelis, rhubarb, rhatany, and salvia are preferably used as adstringent. The amount of the adstringent agents in the inventive preparation is preferably 0 to 30 percent by weight, more preferably 1 to 25 percent by weight, based on the sum of all components in the preparation. The adstringent agents are preferably added in a pure form.

In the present invention usual humectants can optionally be used. Preferred humectants are glycerin, aloe vera, collagen, desamidocollagen, collagen hydrolysates, elastin hydrolysates, hyalomucco solution, fibrostimulin, PN 73, Q 10, water, aloe barbadensis gel, camelia sinensis extract, hedera helix, matricaria (camomile recutita) oil and butylene glykol. The amount of the humectants in the inventive preparation is preferably 0 to 70 percent by weight, more preferably 5 to 50 percent by weight, based on the sum of all components in the preparation.

Furthermore, the preparation of the present invention can optionally comprise usual ethereal oils. Preferred ethereal oils are oils of camomile, lavender, rosemary, camphor, mountain-pine, mint, tea tree and eucalyptus. The amount of the ethereal oils in the preparation of the present invention is preferably 0 to 70 percent by weight, more preferably 3 to 50 percent by weight, based on the sum of all components in the preparation. The ethereal oils are preferably added in a pure form or in the form of extracts or cold-drawn and warm-drawn oils.

The preparation of the present invention can contain all known amino acids and amino acid derivatives. Preferred amino acids and amino acid derivatives are alanine, phenylalanine, cysteine, cystine, proline, tyrosine, serine, histidine, glycin, leucine, isoleucine, valine, tryptophan, arginine, lysin, asparagine and glutamine. Particularly cystine, cysteine, proline, serine, histidine, lycine, leucine, isoleucine, valine, tyrosine, arginine, lysin, asparagine and glutamine are used. Cystine, histidine, glycin, leucine, valine, arginine, lysin and glutamine are especially preferred. The D-form, DL-form and L-form of the amino acids can be used, whereby the L-form is preferred. Examples for amino acid derivatives are N-acetylated forms, e.g. N-acetyl-L-glutamine, N-acetyl-L-tyrosine and N-acetyl-DL-tryptophan. The amino acids and amino acid derivatives can be used solely or in the form of mixtures. The amount of amino acids and amino acid derivatives in the preparation of the present invention is preferably 0.1 to 40 percent by weight, more preferably 0.2 to 30 percent by weight, most preferably 0.2 to 15 percent by weight, based on the sum of all components in the preparation. The amino acids and their derivatives are preferably added in a pure form.

The preparations of the present invention are furthermore characterized by the presence of zinc oxide and/or an inorganic peroxide. As inorganic peroxides preferably zinc peroxide, sodium peroxide, potassium peroxide, calcium peroxide or magnesium peroxide are used. Zinc oxide and/or an inorganic peroxide, for example, can be used to regulate the osmotic pressure. Surprisingly, the combination of amino acids with zinc oxide and/or an inorganic peroxide has a particularly good effect, compared to the use of magnesium peroxide alone. The total amount of zinc oxide and inorganic peroxide in the preparation of the present invention is preferably 0.5 to 50 percent by weight, more preferably 1.5 to 40 percent by weight, based on the sum of all components in the preparation. The amount of inorganic peroxide, if applied topically, should preferably not be larger

than 10 percent by weight, more preferably not larger than 6 percent by weight, most preferably not larger than 3 percent by weight, and, if applied internally, not larger than 20 percent by weight, more preferably not larger than 15 percent by weight. Zinc oxide and inorganic peroxide are preferably added in a pure form.

Optionally, tego-betaine can additionally be present in the preparation of the present invention. The amount of tego-betaine in the inventive preparation is preferably 0 to 25 percent by weight, more preferably 1 to 20 percent by weight and most preferably 5 to 10 percent by weight based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can contain all known bioactive plant substances, also called secondary plant substances. The secondary plant substances used in the present invention particularly comprise carotinoids, phytosterols, saponins, polyphenols, flavonoids, terpenes, phytoestrogens, sulfides, phytin acid and dietary fiber. Of the above-mentioned bioactive plant substances particularly the polyphenols, the flavonoids and the bioflavonoids are used in the present invention. Bioflavonoids of natural sources are especially preferred in the inventive preparation. The bioactive plant substances can be present in the preferred embodiments of the preparation in a preferred amount of 0 to 75 percent by weight, more preferably 2 to 50 percent by weight, based on the sum of all components in the preparation. Preferred natural sources for the bioflavonoids are vegetables, such as pulses, carrots, tomatoes, broccoli and paprika, corn, sesame, citrus fruits, green and black tea, St. John's wort, grapes, etc. The bioactive plant substances are preferably added in the form of extracts.

Optionally, all known unsaturated fatty acids can additionally be used in the preparation of the present invention. Preferably unsaturated fatty acids that are included in vegetable and animal oils (such as fish oil) are used. Polyunsaturated fatty acids from vegetable sources are essential precursors of important regulators of metabolism (eicosanoids and prostaglandines). The amount of unsaturated fatty acids in the inventive preparation is preferably 0 to 70 percent by weight, more preferably 2 to 45 percent by weight, based on the sum of all components in the preparation. Examples for preferred pure vegetable sources of unsaturated fatty acids are evening primrose oil, flax oil, olive oil, wheat germ oil, soy oil, sunflower oil, borage oil, pumpkin seed oil and oil of the seeds of the

redcurrant. The unsaturated fatty acids are preferably added in the form of cold-drawn oils.

Optionally, the preparation of the present invention can furthermore additionally contain usual liposomes, lecithin and lipodermine. Liposomes are important, as they control the release of vitamin A and vitamin E. That way these vitamins are accessible over a longer period of time. The amount of liposomes, lecithin or lipodermine in the inventive preparation is preferably 0 to 30 percent by weight, more preferably 2 to 20 percent by weight, based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can additionally comprise epigallocatechines, preferably recovered from green tea. Through epigallocatechines the aging of the cells can be delayed. Furthermore, they are important as cosubstances and serve to support the effect of micro nutrients, such as vitamins. The amount of the epigallocatechines in the preparation is preferably 0 to 60 percent by weight, more preferably 2 to 30 percent by weight, based on the sum of all components in the preparation. The epigallocatechines are preferably added in a pure form or as extracts.

Optionally, the preparation of the present invention can additionally comprise all known representatives of vitamins and provitamins. Particularly vitamins A, those of the B-complex, C, D and E and β-carotine are preferably used in the preparation. The amount of the vitamins in the preparation of the present invention is preferably 0 to 75 percent by weight, more preferably 5 to 50 percent by weight, based on the sum of all components in the preparation. The vitamins are added both in a natural form as extracts and in a synthetic form (e.g. B-vitamins), whereby differences in the effect of the vitamins are not linked with this fact.

Optionally, the preparation of the present invention can additionally comprise antifungal and antimicrobial components. Antibiotics, bacteriostatics, corticosteroids, cortisones, econazol nitrate, dexametasone, hydroxy benzoate, etc. can be added to the inventive preparation. The amount of the antifungal and antimicrobial components in the preparation is preferably 0 to 60 percent by weight and most preferably 2 to 30 percent by weight, based on the sum of all components in the preparation.

Optionally, the preparation of the present invention can comprise all known adjuvants, additives and carrier substances, the usual binding and adhesive agents and solvents. Preferred examples are milk fat, unhydrogenated, partly hydrogenated or hydrogenated soy fat, soy oil, walnut butter, glycerin, gelatin, pectin, lecithin, β-carotenes, sorbitol solution, iron oxide, titanium dioxide, dyes, fats, waxes, emulgators (e.g. IRICALMIN of the company Pentafarm Ltd., CH), silicones, polyethylenes, polysorbitones, (meth)acryl compounds, talcum, dragantum, xanthan-gum, starch, vaseline, dextrose, saccharin, paraffins, acids, preservatives and fragrances. For example pectin can be used as binding and adhesive agent. Usual amounts of the above-mentioned substances and agents are used, e.g. pectin up to an amount of 10 percent by weight, based on the sum of all components in the preparation.

The preparation of the present invention can be prepared in the usual manner known to every person skilled in the art, for example by combining the active ingredients with suitable, non-toxic, inert, pharmaceutically acceptable solid or liquid carrier materials and optionally the usual additives, adjuvants and solvents to a galenic form of administration. Methods for manufacturing galenic forms of administration, such as ointments and cremes, are for example described in H. Sucker, B. Fuchs, P. Speiser, "Pharmazeutische Technologie", 2nd edition (1991), Georg Thieme Verlag Stuttgart; R. Voigt, "Lehrbuch der pharmazeutischen Technologie", Thieme Verlag, 1976. For the preparation of the present invention all known forms of application are possible. Preferred forms of application are creme, ointment, paste, emulsion, lotion, fluid, solution, gel, powder, spray, gelatin, foam and the like. Forms of application for internal application are for example capsules, tablets, coated tablets, drinking solutions and injection solutions, for example for hypodermal injections. A depot form as form of application is possible as well.

In principle, all known modes of application are possible for the preparation of the present invention. The most preferred one is the topical application, for example effected by applying a corresponding form of application to the skin, e.g. by applying, rubbing on, rubbing gently in, spraying on, dabbing on, etc. Application is also possible in the form of ointment bandages or hypodermal injections. The preparation of the present invention can be applied once or several times a day and both over short and long periods of time. However, the daily dose and the

frequency of the application per day depends on the recipe of the individual inventive preparation.

Depending on the recipe, the preparations of the present invention are suitable as food supplement, cosmetic or pharmaceutical composition, preferably as topical cosmetic or as topical pharmaceutical composition to be applied on the skin and tissue of mammals, and are for example used for the care, protection and prevention of tissue-damaging manifestations and effects and for the treatment of skin and tissue. Depending on their recipe, they are in a preferred embodiment particularly applicable to all skin irritations (e.g. disturbed skin physiology, sun burn), cellulitis, wrinkles, acne, herpes, psoriasis, neurodermatitis, ozone damage, burns, caustic burns, cellular metabolic disturbances and other modifications with accumulation of tissue fluid, fat and other cellular products and cellular catabolites, such as thickenings, edemas, hematomas, and are furthermore applicable to, for example, hemorrhoids, rheumatism, arthrosis, and skin cancer. The preparation can also be applied to mucous membranes, e.g. in the digestive system.

The present invention is further illustrated by an example.

Example 1

A preparation according to the invention having the following components was prepared in the usual manner:

Zinc oxide	8	wt.-%
Sodium peroxide	3	wt.-%
Sodium phosphate	10	wt.-%
Calcium phosphate	6	wt.-%
Calcium chloride	5	wt.-%
Arginine	7	wt.-%
Leucine	8	wt.-%
Asparagine	5.5	wt.-%
Valine	2	wt.-%
Hamamelis	1	wt.-%
Tannin	3	wt.-%
Pectin	1	wt.-%

Tego-betaine	2 wt.-%
Vitamin A	1 wt.-%
Vitamin E	1.5 wt.-%
β-carotine	0.5 wt.-%
Collagen	1.5 wt.-%
Aloe Vera	2 wt.-%
Olive oil	2 wt.-%
Carotinoids	2 wt.-%
Gelatin	1 wt.-%
Liposomes	2 wt.-%
Purified water ad	100 wt.-%

The composition of the above example was applied to one leg of probands. To the other leg control substances (placebo substances; control leg) are applied. The results of the examinations can be summarized as follows:

As acute reaction of the above inventive recipe an increase of microcirculation was found. After about 50 minutes a significant improvement of microcirculation was observed, whereby a maximum increase was reached after about 100 minutes. The significant effective phase was observed after about 120 minutes. On the control leg no changes in microcirculation were observed. As a further reaction caused by the application of the inventive recipe, a reduction of the fat layer on the treated leg could be observed, while there was no modification on the control leg. Through these examinations it was shown that the inventive preparation can significantly improve microcirculation and reduce the fat layer.

Example 2

	Amount (wt.-%)
Aspargine	0.30
Leucine	0.20
Valine	0.30
Arginine	0.20
Zinc peroxide	0.50
Calcium phosphate	4.50
Sodium phosphate	3.50
Zinc oxide transparent	2.00

Calcium chloride	4.00
Magnesium sulfate	3.00
Distilled water	62.90
Hamamelis	2.50
Tego-betaine	2.00
Sorbitol	6.00
Rosemary oil	0.30
Menthol	0.30
Green tea pulvis	1.00
Ivy/bottlebrush (horsetail)/algae/green tea	5.00
Xanthan-gum	1.50

The above inventive preparation was prepared in the usual manner.

First, microcirculation on a specific skin area of a proband was measured. After that, the recipe of example 2 was rubbed gently into this skin area. Microcirculation was measured immediately and, after that, every half hour over a period of 4 hours. Hereby microcirculation was measured in flux units. The measuring results were plotted in relation to time. In comparison with a commercially available product which comprises salts and magnesium peroxide and which was, like the inventive preparation, applied to another skin area, it was observed that microcirculation rose earlier, maintained a higher level over a longer period of time and flattened to the starting value much later when the inventive recipe comprising a combination of certain amino acids and zinc oxide and zinc peroxide was used. The improvement compared to the commercial product was between 7 and 15 % at the corresponding measuring points. The results show the improved systemic, synergistic effect of the inventive recipe compared to the commercial product.

Example 3

A preparation according to the invention having the following components was prepared in the usual manner:

	Amount (wt.-%)
Distilled water	71.15
Calcium phosphate	1.50
Leucine	0.20
Valine	0.30
Arginine	0.20
Aspargine	0.30
Zinc peroxide	0.25
Sodium phosphate	1.50
Zinc oxide transparent	3.00
Karion FP liquid	4.00
Neo Dragold liquid	0.30
Calcium chloride	1.50
Magnesium sulfate	2.50
Green tea pulvis	2.00
Calendula	3.00
Hamamelis	2.50
St. John's wort	3.00
Fragrance 1677	0.30
Teatree oil Australian	1.00
Xanthan-gum	1.50

Example 4

A preparation according to the invention having the following components was prepared in the usual manner:

	Amount (wt.-%)
Distilled water	66.70
Zinc oxide transparent	2.00
Sodium phosphate	3.00
Aspargine	0.05
Calcium phosphate	3.50
Calcium chloride	3.50
Leucine	0.20
Magnesium sulfate	3.00
Zinc peroxide	0.30
Tego-betaine	2.00
Hamamelis	2.50
Sorbitol	5.00
YLANG-YLANG OIL II	0.10
Lotus fragrance – ethereal oil mixture	0.10
Menthol	0.05
Green tea,pulvis	0.50
IRICALMIN	3.00
GLYCODERM	3.00
Xanthan-gum	1.50

In further applications of recipes which are part of the invention, significantly positive effects regarding aging, elasticity, moisture, wrinkling and tightening of the skin were observed.

PCT/DE99/02202
Mandorlo Investment GmbH et. al.

Claims as filed on August 23, 2000

1. Use of a preparation comprising:
   (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
   (b) at least one amino acid, and
   (c) zinc oxide and/or an inorganic peroxide
   for the preparation of a pharmaceutical composition for the treatment of skin irritations, sun burn, cellulitis, wrinkles, acne, herpes, neurodermatitis, ozone damage, burns, caustic burns, thickenings, edemas, hematomas, hemorrhoids, rheumatism, arthrosis and skin cancer.

2. Preparation for the topical application comprising the following components:
   (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
   (b) at least one amino acid,
   (c) zinc oxide and/or an inorganic peroxide, and
   (d) at least one secondary plant substance.

3. Preparation comprising the following components:
   (a) at least one salt selected from alkali metal salts, alkaline earth metal salts and other minerals,
   (b) at least one amino acid,
   (c) zinc oxide and/or an inorganic peroxide,
   (d) at least one secondary plant substance, and
   (e) at least one polyunsaturated fatty acid of vegetable sources.

4. Preparation according to claim 2, characterized in that it comprises at least one unsaturated fatty acid.

5. Preparation according to any one of claims 2 to 4, characterized in that it additionally comprises tego-betaine and/or at least one epigallocatechine and/or at least one trace element.

6. Preparation according to any one of claims 2 to 5, characterized in that it additionally comprises at least one liposome and/or at least one vitamin.

7. Preparation according to any one of claims 2 to 6, characterized in that it additionally comprises at least one adstringent agent and/or at least one humectant and/or at least one ethereal oil.

8. Preparation according to any one of claims 2 to 7, characterized in that it additionally comprises antifungal and/or antimicrobial components.

9. Preparation according to any one of claims 2 to 8, characterized in that it additionally comprises at least one component selected from carrier substances, adjuvants, additives, binding agents, adhesive agents and solvents.

10. Preparation according to any one of claims 2 to 9, comprising the following components:
    (a) 10 to 90 wt.-% of a salt, selected from alkali metal salts, alkaline earth metal salts and other minerals,
    (b) 0.1 to 40 wt.-% of an amino acid, and
    (c) a total amount of zinc oxide and inorganic peroxide of 0.5 to 50 wt.-%, based on the sum of all components in the preparation.

11. Preparation according to any one of the claims 2 to 10, comprising the following components:
    (a) at least one metal salt selected from sodium, potassium, magnesium, calcium, silicon, zinc, manganese, copper, iron, fluorine, chlorine, bromine, iodine and phosphorus,
    (b) at least one amino acid or amino acid derivative selected from cystine, cysteine, proline, serine, histidine, glycin, leucine, isoleucine, valine, tyrosine, arginine, lysin, asparagine and glutamine, and
    (d) zinc oxide and/or an inorganic peroxide.

12. Preparation according to any one of claims 2 to 11, characterized in that the inorganic peroxide is zinc peroxide, sodium peroxide, potassium peroxide, calcium peroxide or magnesium peroxide.

13. Use of a preparation according to any one of claims 3 to 12 for topic application.

14. Use of a preparation according to any one of claims 2 to 13 as a cosmetic.

15. Use of a preparation according to any one of claims 3 to 13 as a pharmaceutical composition.

16. Use of a preparation according to any one of claims 2 to 13 for the preparation of a pharmaceutical composition for the treatment of skin irritations, sun burn, cellulitis, wrinkles, acne, herpes, neurodermatitis, ozone damage, burns, caustic burns, thickenings, edemas, hematomas, hemorrhoids, rheumatism, arthrosis and skin cancer.

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Internationales Büro
INTERNATIONALE ANMELDUNG VERÖFFENTLICHT NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT)

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Veröffentlicht
Mit internationalem Recherchenbericht.

(88) **Veröffentlichungsdatum des internationalen Recherchenberichts:** 20. April 2000 (20.04.00)

(54) **Title:** SKIN AND TISSUE CARE AND/OR TREATMENT AGENT

(54) **Bezeichnung:** MITTEL ZUR PFLEGE UND/ODER BEHANDLUNG VON HAUT UND GEWEBE

(57) **Abstract**

The invention relates to a skin and tissue care and/or treatment agent. In particular, it relates to an agent for caring for and protecting skin and tissue, for preventing tissue–damaging manifestations and effects and for treating skin and tissue. The inventive agent comprises at least one salt chosen from alkaline and alkaline earth metal salts and other mineral substances and is characterised in that it contains at least one amino acid and zinc oxide and/or an inorganic peroxide. The inventive agent can optionally also contain an astringent, a binding and bonding agent, a moisturiser, an ethereal oil, tego–betaine, secondary plant substances such as epigallocatechine, unsaturated fatty acids, liposomes, vitamins, trace elements and antifungal and/or antimicrobial components.

(57) **Zusammenfassung**

Die Erfindung betrifft ein Mittel zur Pflege und/oder Behandlung von Haut und Gewebe. Insbesondere betrifft die Erfindung ein Mittel zur Pflege, zum Schutz, zur Vorbeugung gewebsschädigender Manifestationen und Einwirkungen und zur Behandlung von Haut und Gewebe, welches mindestens ein Salz, ausgewählt aus Alkali– und Erdalkalimetallsalzen und anderen Mineralstoffen, umfaßt, dadurch gekennzeichnet, daß es mindestens eine Aminosäure und Zinkoxid und/oder ein anorganisches Peroxid enthält. Das erfindungsgemäße Mittel kann zusätzlich gegebenenfalls ein adstringierendes Mittel, ein Binde– und Haftmittel, ein Feuchtigkeitsmittel, ein etherisches Öl, Tego–Betain, sekundäre Pflanzenstoffe, wie Epigallocatechine, ungesättigte Fettsäuren, Liposomen, Vitamine, Spurenelemente und antimykotische und/oder antimikrobische Komponenten umfassen.

A1820 US

Attorney Docket No. 0147-0220P

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Insert Title: SKIN AND TISSUE CARE AND/OR TREATMENT PREPARATION

Fill in Appropriate Information - For Use Without Specification Attached:

the specification of which is attached hereto. If not attached hereto,
the specification was filed on January 12, 2001 as
United States Application Number 09/743,577 ;
and amended on January 12, 2001 (if applicable) and/or
the specification was filed on July 15, 1999 as PCT
International Application Number PCT/DE99/02202 ; and was
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I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

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Insert Priority Information: (if appropriate)

Prior Foreign Application(s)			Priority Claimed	
198 31 798.0 (Number)	Germany (Country)	July 15, 1998 (Month/Day/Year Filed)	☒ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
(Number)	(Country)	(Month/Day/Year Filed)	☐ Yes	☐ No
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(Application Number)	(Filing Date)	(Status - patented, pending, abandoned)
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